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| APPLICATION NO.                 | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|----------------|----------------------|---------------------|------------------|
| 10/621,195                      | 07/15/2003     | Robert M. Burk       | 17120FWCCON6 (AP)   | 2332             |
| Allergan, Inc.                  | 7590 12/23/201 | EXAMINER             |                     |                  |
| LEGAL DEPA                      | ARTMENT T2-7H  | FAY, ZOHREH A        |                     |                  |
| 2525 Dupont I<br>Irvine, CA 926 |                |                      | ART UNIT            | PAPER NUMBER     |
| 11 1110, 011 520                |                |                      | 1627                |                  |
|                                 |                |                      |                     |                  |
|                                 |                |                      | MAIL DATE           | DELIVERY MODE    |
|                                 |                |                      | 12/23/2010          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

| Application No. | Applicant(s)    |  |  |  |  |
|-----------------|-----------------|--|--|--|--|
| 10/621,195      | BURK, ROBERT M. |  |  |  |  |
| Examiner        | Art Unit        |  |  |  |  |
| ZOHREH A. FAY   | 1627            |  |  |  |  |

| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |  |  |  |  |  |
|--|---|--|--|--|--|--|
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of them may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely lited after SIX (6) MONTHS from the mailing date of this communication.  - IN Depend for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. |   |  |  |  |  |  |
| <ul> <li>Two person or pay as species over, in the facilities of the pay and we require six, of year ATT shall be interested as a communication.</li> <li>Failure to reply within the set centerinde period for reply will, by static, cause the application to become ABANDONED (35 &amp; \$135).</li> <li>Any reply received by the Office later than three months after the making date of this communication, even if timely filed, may reduce any earned pattern them adjustment. See 37 CPR 1.74(b).</li> </ul>        |   |  |  |  |  |  |
| Status   |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on   |   |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This action is non-final.  |   |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |   |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |
| 4) Claim(s) 1 and 3-6 is/are pending in the application.   |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1 and 3-6</u> is/are rejected.   |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.  |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |   |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |  |  |  |  |  |
|  |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
| Certified copies of the priority documents have been received in Application No.   |   |  |  |  |  |  |
| Copies of the certified copies of the priority documents have been received in Application vol.  |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |
|  |   |  |  |  |  |  |
|  |   |  |  |  |  |  |
| Attachment(s)  |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patient Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date  |   |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-98108)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application   | _ |  |  |  |  |  |

| US | Patent | and | Trade | mark | Office |
|----|--------|-----|-------|------|--------|
|    | OL-32  |     |       |      |        |

Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of informal Patent Application
6) Other: \_\_\_\_\_.

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#### DETAILED ACTION

Claims 1 and 3-6 are presented for examination.

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2010 has been entered.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,124,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap. The claims of the US patent are drawn to a prostaglandin compound with R being specific substituted hetero aryl compounds for the treatment of intraocular pressure. The claims of the instant application are drawn to a prostaglandin compound having R a substituted hetero aryl compound in general. The claims of the US Patent are within the scope of the claims of the instant application.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1 and 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed. had possession of the claimed invention. the claims are drawn to the phrase "R is a substituted hetero aryl radical". The specification discloses a few hetero aryl radicals, such as, thienyl, furanyl and thiazolyl within the scope of what is claimed. However there is no evidence that there is any per se structure/function relationship between the disclosed hetero aryl radicals and any others that might be found using the claimed method. Structural identifying characteristics of group of hetero aryl radicals are not disclosed. Therefore, the claimed invention is not supported by an adequate written description. To provide adequate written description an evidence of possession of the claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and /or chemical properties, Functional characteristics, structure/function correlation, or any combination thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone Application/Control Number: 10/621,195 Page 5

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF /Zohreh A Fay/ Primary Examiner, Art Unit 1627